



AFFIDAVIT OF ACCURACY

This is to certify the document, **Correspondence regarding Manufacturing contract of March 23, 2003**, has been translated from Spanish into English by staff members of TransPerfect Translations familiar with both the Spanish into English languages and is to the best of our knowledge, ability and belief, a true and accurate translation.

A handwritten signature in dark ink, appearing to read 'Susan Christian'.

Susan Christian
TransPerfect Translations, Inc.
15 Broad St., Suite 305
Boston, MA 02109

Sworn to before me this
29th day of October 2004

A handwritten signature in dark ink, appearing to read 'Notary Public'.

Signature, Notary Public
Commonwealth of Massachusetts
Commission Expires August 14, 2009

[logo]

Laboratorios Belmac, S.A.

LABORATORIOS ETHYPHARM, S.A.

Mr. Adolfo de Basilio

Calle Marqués de la Ensenada, 16

28004 MADRID

Madrid, November 14, 2001

Dear Sirs,

We are writing to you in your capacity of counterpart under the "Manufacturing Contract" of OMEPRAZOL microgranules, signed on March 23, 2000.

Using the right granted to us under section G of said Contract and complying with the notice mandated therein, we are hereby communicating our decision to cancel said Manufacturing Contract of OMEPRAZOL microgranules, which notice of cancellation is issued more than four (4) months before March 23, 2002.

Consequently, we indicate that as of said date, you must consider the Manufacturing Contract mentioned above cancelled for all purposes.

Sincerely,

[signature]

Adolfo Herrera

General Director

P.S.: Since the "Manufacturing Contract" of OMEPRAZOL microgranules of March 23, 2000 will be cancelled on March 23, 2002, I am communicating that, as of now, we are completely available to negotiate with you a new Manufacturing Contract in which, taking into account the current circumstances—which are different than those that motivated the 2000 contract—the needs of Laboratorios Ethypharm, S.A. may be fully satisfied.

[see original for address information]

[logo]

Laboratorios Belmac, S.A.

LABORATORIOS ETHYPHARM, S.A.

Mr. Adolfo de Basilio

Calle Marqués de la Ensenada, 16

28004 MADRID

Madrid, November 14, 2001

Dear Sirs,

We are writing to you in your capacity of counterpart under the "Purchase Promise Letter" signed on March 23, 2000.

Using the right granted to us under Specification 3 of said Letter and complying with the prior notice mandated, we are hereby communicating our decision to cancel said Purchase Promise, which notice of cancellation is issued more than four (4) months before March 23, 2002.

Consequently, we are indicating that as of said date, you must consider said Purchase Promise cancelled for all purposes.

Sincerely,

[signature]

Adolfo Herrera

General Director

[see original for address information]

A-606

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**ETHYPHARM S.A. FRANCE &
ETHYPHARM S.A. SPAIN,**

Plaintiffs

V.

BENTLEY PHARMACEUTICALS, INC.

Defendant.

C.A. No. 04-1300 (SLR)

JURY TRIAL DEMANDED

**DECLARATION OF JAMES R. MURPHY IN SUPPORT OF DEFENDANT
BENTLEY PHARMACEUTICALS, INC.'S MOTION TO DISMISS**

Of Counsel:
Craig E. Stewart
Marc J. Goldstein
PALMER & DODGE LLP
111 Huntington Avenue
Boston, MA 02199
Telephone: (617) 239-0100

Dated: November __, 2004

Richard L. Horwitz (#2246)
David E. Moore (#3898)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 North Market Street
P.O. Box 951
Wilmington, DE 19899-0951
Telephone: (302) 984-6000

Attorneys for Defendant

I, James R. Murphy, declare under penalty of perjury as follows:

1. I am the chairman, president, chief executive officer, and a director of Bentley Pharmaceuticals, Inc. ("Bentley"). I have personal knowledge of the facts stated in this declaration, and if called as a witness, could competently testify to them. I make this declaration in support of Bentley's Motion to Dismiss for Failure to Join a Necessary Party.

2. I have been a director of Bentley since 1993, president since 1994, and chairman and CEO since 1995.

Structure, Organization, and Operations of Bentley Pharmaceuticals, Inc.

3. Bentley is a specialty pharmaceutical company focusing on the development and licensing of drug delivery technologies and generic and branded pharmaceutical products. Bentley is a Delaware company with its principal place of business in Exeter, New Hampshire.

4. Bentley owns a 15,700 square foot commercial building on 14 acres of land in Exeter, New Hampshire, which houses its corporate headquarters and a research and development laboratory. Bentley has 17 employees.

Bentley is a drug delivery company applying enabling permeation technology to enhance the absorption of drugs through the skin (such as the transdermal delivery of testosterone and the intranasal spray administration of insulin). Bentley conducts research in the USA for itself and under contract for others.

5. Bentley has a wholly-owned subsidiary, Pharma de Espana ("Pharma"). Pharma is a Delaware Corporation which in turn has two wholly-owned subsidiaries

operating outside the United States: Laboratorios Belmac, S.A. ("Belmac") and Bentley API, S.L. Belmac in turn has two subsidiaries of its own: Laboratorios Rimafar, S.L. and Laboratorios Davur, S.L. both Spanish corporations. Each of these subsidiary corporations are separately capitalized, own their own assets (including intellectual and real property), have independent management groups with day-to-day responsibility for operations, and maintain separate employees.

6. Each of Bentley's subsidiaries separately prepares financial statements, which are audited by Deloitte and Touche S.A., and filed with appropriate entities in Spain. In accordance with Generally Accepted Accounting Principles, Bentley's financial statements incorporate Bentley's activities as well as those of the above wholly-owned subsidiaries. Deloitte and Touche USA audits Bentley's financial statements in the United States.

Structure and Organization of Bentley's Subsidiary Laboratorios Belmac, S.A.

7. Even though Belmac is a subsidiary of Bentley, Belmac is capitalized separately from Bentley and operates independently of Bentley. Belmac has its own management team and personnel, assets, expenditures, investments, budget, liabilities, intellectual property, and bank accounts. Belmac is authorized to issue its own stock, may seek its own capital, and is not dependent on Bentley for funding. Belmac elects its own board of directors. Belmac guarantees its own debts.

8. Belmac has 312 employees in Spain. Belmac pays these employees from its own bank accounts. Belmac hires its own employees and makes employment decisions regarding these employees, including salaries.

9. Adolfo Herrera is the general manager of Belmac. He has significant autonomous authority over the operations of Belmac. The extent of Mr. Herrera's

authority is contained in the delegation of power from the Belmac board of directors to the Belmac general manager, which is required under Spanish law. In June and November 1999, the Belmac board authorized Mr. Herrera to exercise the following powers, among others:

- (a) execute and comply with contracts related to Belmac's business;
- (b) enter into encumbrances, liens and any other guarantees;
- (c) open and maintain bank accounts;
- (d) buy and sell all kinds of goods and intellectual property up to 20 million pesetas per transaction;
- (e) enter into joint ventures;
- (f) represent the company before the Spanish Ministry of the Economy and Treasury; and
- (g) institute and defend legal cases and claims;

10. The Belmac board had granted similar delegations of powers to Mr. Herrera and previous general managers throughout the time that Belmac interacted with Ethypharm.

11. As a result of this significant delegation of responsibility, Mr. Herrera maintained and continues to maintains day-to-day control over the operations of Belmac and did not and does not have to seek my authorization or direction in the day-to-day operation of the plant or in Belmac's dealings with Ethypharm. Indeed, Mr. Herrera need not consult with Belmac's board or Bentley unless he will exceed the delegation of responsibility.

12. Since 1994, I have held, and still hold, the title of President of Belmac. As Belmac's President, I only address(ed) major issues that exceed the power delegated to Mr. Herrera and that therefore require(d) my signature. I hold the title of President so that Bentley can have some oversight over Belmac, which produces a significant portion of Bentley's revenue. Nevertheless, my involvement with Belmac is limited to discussing general strategies with Mr. Herrera and to addressing issues that exceed the power delegated to Mr. Herrera. I am not, and was not, involved in Belmac's operations. Prior to Mr. Herrera's appointment as general manager of Belmac, I spent one week out of every few months in Spain in my capacity as Belmac's President. Since Mr. Herrera's appointment, however, I have only gone to Spain three or four times per year in my capacity as Belmac's President.

13. Belmac prepares its own financial statements, which are audited by Deloitte and Touche, S.A., a Spanish company. These financial statements are filed with the proper authorities in Spain. Belmac negotiates its own agreements and contracts and does not need Bentley's approval to do so.

14. Belmac owns an 80,000 square foot facility in Zaragoza, Spain, which houses its manufacturing plant, warehouse, research and development laboratory, and office space.

Directors and Officers of Belmac and Bentley

15. The officers of Bentley are: Michael McGovern (vice chairman), Dr. Robert Stote (senior vice president and chief medical officer), Michael D. Price (vice president, chief financial officer, treasurer and secretary), and Robert Gyurik (vice president of pharmaceutical development). In addition to the officers, the following are

directors of Bentley: Miguel Fernandez, John W. Spiegel, Mike McGovern, Edward Robinson, and F. Ross Johnson.

16. While both I and Michael Price are also officers of Belmac, Belmac's board of directors also includes Adolfo Herrera. In addition, all of the senior management team of Belmac is distinct from Bentley. Bentley's board of directors does not control or direct Belmac's operations.

Belmac is not an Agent of Bentley

17. Belmac is not an agent of Bentley. Belmac does not have either express or apparent authority to act on Bentley's behalf. Bentley is a shareholder of Belmac. Bentley did not and does not now direct or control the day-to-day operations of Belmac. Belmac controls its own day-to-day operations, including the manufacture of omeprazole.

Belmac's Relationship with Ethypharm and its Responsibility for Production of Omeprazole

18. Belmac, not Bentley, entered into agreements with Ethypharm regarding the production of omeprazole, including any confidentiality or nondisclosure agreements. Bentley never entered into an agreement with Ethypharm regarding the production of omeprazole. The terms of any agreements between Belmac and Ethypharm were negotiated by representatives of Belmac, specifically the Belmac general managers, not Bentley. Belmac never acted on Bentley's behalf during these negotiations and Bentley never granted Belmac the authority to act on Bentley's behalf in negotiations or contracting with Ethypharm. Bentley did not have any rights, obligations, or duties under these agreements as it was not a signatory to them.

19. Neither I nor any other Bentley employee was involved on behalf of Bentley in the negotiations of the terms and conditions of the March 23, 2000

manufacturing contract between Belmac and Ethypharm. Similarly, neither I nor any other Bentley employee was involved on behalf of Bentley in subsequent discussions between Belmac and Ethypharm in January and February 2002 regarding the expiration of that agreement.

20. Before, during, and after the contract with Ethypharm to manufacture omeprazole, Belmac manufactured and produced omeprazole in the Zaragoza facility. Belmac, not Bentley, controlled the manufacture of omeprazole in the Zaragoza facility during the contract with Ethypharm and continues to control the production of omeprazole at the Zaragoza facility. Bentley did not and does not participate in the manufacture and production of omeprazole in Zaragoza.

21. Belmac developed its own omeprazole manufacturing process in Spain without Bentley's involvement. Belmac used its own funds to finance the manufacture of omeprazole and the necessary clinical trials of the omeprazole manufacturing process that Belmac developed.

22. Belmac has filed for five Spanish patents and two Patent Cooperation Treaty patents (with effects in Spain). Four of these seven patents relate to the production of omeprazole. Three of those seven patents have been granted and Belmac is the owner of those patents. When the remaining patents are granted, Belmac will be the patent holder. Bentley does not own any patents pertaining to the manufacture of omeprazole, lansoprazole, or related products in Spain.

23. Belmac owns and maintains the registration files for more than 40 compounds that Belmac filed with the Spanish Ministry of Health. The Spanish Ministry

of Health's approvals of Belmac's omeprazole compounds were issued in Belmac's name, not Bentley's, for the manufacture and distribution of omeprazole in Spain.

Jim Murphy's Interactions with Ethypharm

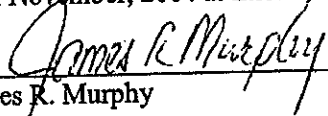
24. When I have directly interacted with Ethypharm, it has been in two distinct contexts. First, at various times in the past Ethypharm would request information or meetings with me regarding the Belmac-Ethypharm relationship in my capacity as the President of Belmac. To the extent I participated in these issues, it was solely in my capacity as an officer of Belmac and not on behalf of Bentley. Second, the only times in which I interacted with Ethypharm on behalf of Bentley was between 1995 and 2000, when I discussed or corresponded with Ethypharm on behalf of Bentley concerning possible direct business collaboration between the two companies. These contacts were sporadic and did not concern the omeprazole business between Ethypharm and Belmac.

25. The October 6, 2000 fax cited in Ethypharm's Complaint pertained to Ethypharm's contemplated closure of its Spanish operations. At that time, Ethypharm had already started to lay personnel off. Bentley was considering the purchase of Ethypharm's Spanish operations or, in the alternative, running Ethypharm's existing operations in Spain. Ethypharm had a number of customers who bought omeprazole and this fax involved a proposal to switch the servicing of their customers to Belmac's operations.

26. Likewise, I wrote the January 28, 1997 fax cited in Ethypharm's complaint in my capacity as President of Belmac and not in my capacity as an officer of Bentley.

27. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 3rd day of November, 2004 at Exeter, New Hampshire.


James R. Murphy

CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document to be served upon the attorney of record for each other party by mail on November __, 2004.

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

ETHYPHARM S.A. FRANCE AND
ETHYPHARM S.A. SPAIN,

Plaintiffs,

Civil Action No. 04-1300-SLR

v.

BENTLEY PHARMACEUTICALS, INC.,

Defendant.

**SUPPLEMENTAL DECLARATION OF ADOLFO HERRERA IN SUPPORT OF
DEFENDANT BENTLEY PHARMACEUTICALS, INC.'S
MOTION FOR SUMMARY JUDGMENT**

John L. Reed (I.D. 3023)
Denise Seastone Kraft (I.D. 2778)
Joseph B. Cicero (I.D. 4388)
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919 N. Market Street, 15th Floor
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(302) 777-7770
(302) 777-7263

OF COUNSEL:

Craig E. Stewart
Joseph P. Mingolla
Veronica C. Abreu
EDWARDS ANGELL PALMER & DODGE LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0100

August 25, 2006

BOS111 12061124.5



I, Adolfo Herrera, declare under penalty of perjury as follows:

1 I was hired as the Deputy General Manager of Laboratorios Belmac, S.A. ("Belmac") in October 1997, and I have been the General Manager of Belmac since June of 1999. I have personal knowledge of the facts stated in this supplemental declaration, and if called as a witness, could competently testify to them. I make this supplemental declaration in support of Defendant Bentley Pharmaceuticals, Inc.'s Motion for Summary Judgment.

2. Belmac is a company incorporated under the laws of Spain with its headquarters in Madrid. Belmac is in the business of developing, manufacturing, selling and marketing pharmaceutical products.

3. Under Spanish law, a pharmaceutical company must receive official approval from the Spanish Ministry of Health to manufacture and market pharmaceutical drugs, including omeprazole and other pellet drugs, in Spain. To receive approval to manufacture pharmaceutical products in Spain, a pharmaceutical company must have a manufacturing plant in Spain.

4. Since the late 1990s, Belmac has earned substantial revenue from its development, manufacture, sale and marketing of pharmaceutical products in Spain, considerably more than its parent corporation, Bentley Pharmaceuticals, Inc. Its net sales from 1998 – 2001 were, respectively, \$15.1 million, \$20.2 million, \$18.5 million and \$26.4 million.

5. Belmac maintains bank accounts in its own name in Spain.

6. Belmac pays taxes in its own name to the Spanish taxing authorities.

7. From approximately late 1992 through August of 2003, Belmac

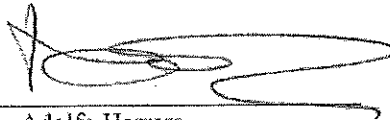


manufactured several pharmaceutical products for Ethypharm, including omeprazole, lansoprazole, aspirin, vincamine, indometacine, and piroxicam at Belmac's Zaragoza facility. As agreed by Ethypharm, Belmac manufactured omeprazole to its customers, as well as it marketed omeprazole under its own brand, "Belmazol", to wholesalers, hospitals and pharmacies.

8. I was never directed or instructed by either Mr. Murphy or anyone else employed by Bentley Pharmaceuticals, Inc. ("Bentley") concerning what technology Belmac should use to manufacture omeprazole in Spain.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

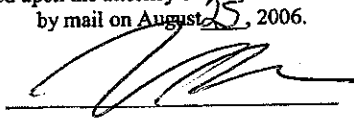
Executed on this 23rd day of August, 2006 at Madrid, Spain.

A handwritten signature in black ink, appearing to read 'Adolfo Herrera', is written over a horizontal line.

Adolfo Herrera

CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document
to be served upon the attorney of record for each other party
by mail on August 15, 2006.

A handwritten signature in black ink, appearing to be "J. L. Smith", is written over a horizontal line.

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

ETHYPHARM S.A. FRANCE AND
ETHYPHARM S.A. SPAIN,

Plaintiffs,

v.

BENTLEY PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 04-1300-SLR

**SUPPLEMENTAL DECLARATION OF JAMES R. MURPHY IN SUPPORT OF
DEFENDANT BENTLEY PHARMACEUTICALS, INC.'S
MOTION FOR SUMMARY JUDGMENT**

John L. Reed (I.D. 3023)
Denise Seastone Kraft (I.D. 2778)
Joseph B. Cicero (I.D. 4388)
EDWARDS ANGELL PALMER & DODGE LLP
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OF COUNSEL:

Craig E. Stewart
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Veronica C. Abreu
EDWARDS ANGELL PALMER & DODGE LLP
111 Huntington Avenue
Boston, MA 02199
(617) 239-0100

August 25, 2006

I, James R. Murphy, declare under penalty of perjury as follows:

1. I am the chairman, chief executive officer, and a director of Bentley Pharmaceuticals, Inc. ("Bentley") and the President of Laboratorios Belmac, S.A. ("Belmac"). I have personal knowledge of the facts stated in this supplemental declaration, and if called as a witness, could competently testify to them. I make this supplemental declaration in support of Bentley's Motion for Summary Judgment.

2. Bentley is headquartered in Exeter, New Hampshire, and has no other offices.

3. *Bentley has never manufactured (or had the experience to manufacture) omeprazole or any other pellet drug at issue in this case.*

4. Bentley is not, and was never, authorized by the Spanish Ministry of Health to manufacture or market omeprazole or any other drug in Spain.

5. Under Spanish law, a pharmaceutical company must receive official approval from the Spanish Ministry of Health to manufacture and market pharmaceutical drugs, including omeprazole or other pellet drugs, in Spain. Bentley cannot obtain approval to manufacture pharmaceutical products in Spain because Bentley does not have a manufacturing plant in Spain.

6. Prior to its acquisition in 1992 by Bentley (which was then a Tampa, Florida-based company called Belmac Corporation), Laboratorios Belmac was known as "Rimafar." Rimafar was incorporated in 1988 by its general manager, Angel Perez de Ayala ("Mr. Ayala"), who remained as General Manager of Laboratorios Belmac until late 1994. The newly named Laboratorios Belmac, S.A. kept its administrative offices in Madrid, and continued to own and operate Rimafar's manufacturing facility, warehouse,

laboratory and related offices located in an 80,000 square foot facility in Zaragoza, Spain.

7. Angel Perez de Ayala was the general manager of Belmac from early 1992 until approximately mid-to-late 1994. For a few months after Mr. Ayala's departure from Belmac, Belmac did not have a general manager. Because Belmac lacked a general manager, I took a more active role in the operations of Belmac from approximately late 1994 to early 1995. In 1995, I promoted Dr. Clemente Gonzalez Azpeitia to the position of general manager of Belmac.

8. Belmac's general managers were never directed or instructed by either me or anyone else employed by Bentley, to sell omeprazole or other pellet drugs to actual or potential customers of Ethypharm S.A. France and/or Ethypharm S.A. Spain (collectively, "Ethypharm"), either before or after March 23, 2002, the date that the March 23, 2000 Manufacturing Agreement for omeprazole between Belmac and Ethypharm S.A. Spain expired.

9. Belmac's general managers were never directed or instructed by either me or anyone else employed by Bentley or its predecessor, Belmac Corporation, concerning what technology Belmac should use to manufacture omeprazole in Spain.

10. Neither Bentley nor any of its employees ever executed a confidentiality agreement with Ethypharm concerning omeprazole and/or micropellet technology. In 1995, I signed on behalf of Bentley (which was then still known as Belmac Corporation), a mutual confidentiality agreement with Ethypharm concerning the possible acquisition of Conrex Company, a U.S. company which researched and developed transdermal products. This agreement had nothing to do with Belmac, omeprazole, or other pellet drugs at issue in this case. In 2000, I signed on behalf of Bentley a mutual confidentiality

agreement with Ethypharm concerning Bentley's technology with respect to the transdermal absorption of drugs (through the skin), which again had nothing to do with Belmac's manufacture of omeprazole or any other drug at issue in this case.

11. Neither Bentley nor any of its employees ever sold omeprazole or other pellet drugs to Ethypharm's customers or ever contacted Ethypharm's customers concerning their purchase of pharmaceutical products manufactured by Belmac.

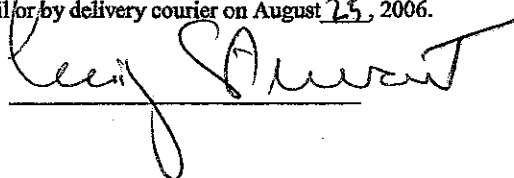
I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 26 day of August, 2006 at Exeter, New Hampshire.


James R. Murphy

CERTIFICATE OF SERVICE

I hereby certify that I caused a true copy of the above document to be served upon the attorney of record for each other party by mail or by delivery courier on August 25, 2006.


Kerry S. Ament

Elzaburu, S. A.
MIGUEL ANGEL, 21
28010 MADRID

AL JUZGADO DE LO MERCANTIL DE MADRID

PARTE ACTORA

DEMANDANTE: ETHYPHARM, S.A.
PROCURADORA: D^a ALMUDENA GALÁN GONZÁLEZ
LETRADO: D. ANTONIO CASTÁN PÉREZ-GÓMEZ

PARTE DEMANDADA

LABORATORIOS BELMAC, S.A.

PROCEDIMIENTO: JUICIO ORDINARIO

OBJETO: INFRACCIÓN DERECHOS DE PATENTE

CONFIDENTIAL
EP 004880

A-624

HECHOS

PRIMERO.- LA COMPAÑÍA DEMANDANTE ETHYPHARM, S.A. Y EL PLANTEAMIENTO GLOBAL DE LA ACCIÓN QUE SE INTERPONE

SEGUNDO.- LA PATENTE DE INVENCION N° 9301319 QUE SIRVE DE BASE A LA ACCIÓN

TERCERO.- LAS RELACIONES COMERCIALES MANTENIDAS ENTRE LAS PARTES A PROPÓSITO DEL OMEPRAZOL FABRICADO CONFORME A LA PATENTE N° 9301319

- A) La demandada LABORATORIOS BELMAC, S.A.
- B) Los acuerdos suscritos por LABORATORIOS BELMAC, S.A. con ETHYPHARM, S.A. para la fabricación del Omeprazol con arreglo a la patente ES 9301319
- C) La maquinaria, propiedad de ETHYPHARM, S.A., instalada en la fábrica de LABORATORIOS BELMAC, S.A. para la producción del Omeprazol conforme a la patente ES 9301319
- D) El reconocimiento explícito por LABORATORIOS BELMAC, S.A. de la tecnología inherente a la patente ES 9301319 de ETHYPHARM, S.A. y del esfuerzo empresarial realizado por la actora en la planta de la demandada
- E) El Omeprazol fabricado por LABORATORIOS BELMAC, S.A. bajo la patente de ETHYPHARM, S.A.

CONFIDENTIAL
EP 004881

CUARTO.- LA RUPTURA UNILATERAL DE LAS RELACIONES
COMERCIALES POR PARTE DE LABORATORIOS
BELMAC, S.A.

- A) La resolución del contrato de fabricación en
noviembre de 2001 por LABORATORIOS
BELMAC, S.A.
- B) Las negociaciones emprendidas y el compromiso
contraído por LABORATORIOS BELMAC, S.A.
de cesar en toda explotación de la patente y
maquinaria de ETHYPHARM, S.A. a partir del 23
de marzo de 2002
- C) La retirada final, después de varios intentos, de la
maquinaria de ETHYPHARM, S.A. en septiembre
de 2003

QUINTO.- LA EXPLOTACIÓN INCONSENTIDA POR
LABORATORIOS BELMAC, S.A. DE LA PATENTE Y
TECNOLOGÍA DE ETHYPHARM, S.A. ENTRE EL 23 DE
MARZO DE 2002 Y EL 19 DE DICIEMBRE DE 2002

- A) La aparición en el mercado de productos de
Omeprazol fabricados por LABORATORIOS
BELMAC, S.A. con posterioridad al 23 de marzo
de 2002
- B) Las diligencias de comprobación de hechos
practicadas en Zaragoza en la planta de
LABORATORIOS BELMAC, S.A. el 19 de
diciembre de 2002
- C) La verificación técnica de la infracción: informe
pericial que se aporta en relación con la
documentación aprehendida en Zaragoza

CONFIDENTIAL
EP 004882

SEXTO.- LA PERSISTENCIA POR LABORATORIOS BELMAC, S.A. EN LA INFRACCIÓN CON POSTERIORIDAD A LA PRÁCTICA DE LAS DILIGENCIAS DE COMPROBACIÓN DE HECHOS EN DICIEMBRE DE 2002

- A) Las cápsulas de Omeprazol fabricadas por LABORATORIOS BELMAC, S.A. con posterioridad al 19 de diciembre de 2002
- B) La inexistencia de cambio alguno en la formulación: falta de nuevos registros sanitarios obtenidos por LABORATORIOS BELMAC, S.A. para la comercialización de Omeprazol
- C) La irrelevancia de las patentes posteriores obtenidas por LABORATORIOS BELMAC, S.A. en relación con el Omeprazol
- D) La verificación técnica adicional que se aporta en relación con el Omeprazol actual fabricado por LABORATORIOS BELMAC, S.A.

SÉPTIMO.- LOS DAÑOS Y PERJUICIOS QUE SE DERIVAN DE LA VIOLACIÓN DE LA PATENTE DE ETHYPHARM, S.A. Y DEL COMPORTAMIENTO DESLEAL DE LABORATORIOS BELMAC, S.A.

- A) El margen que representaba para ETHYPHARM, S.A. la venta del Omeprazol fabricado por LABORATORIOS BELMAC, S.A.
- B) La cuantificación del daño en la fabricación y venta de Omeprazol a partir del 23 de marzo de 2002

CONFIDENTIAL
EP 004883

FUNDAMENTOS DE DERECHO

-I-

PRESUPUESTOS PROCESALES

1. **Jurisdicción y clase de juicio**
2. **Competencia objetiva**
3. **Competencia territorial**
4. **Legitimación**
5. **Postulación**
6. **Actividad probatoria**

-II-

DERECHOS QUE SE DERIVAN DE LA TITULARIDAD POR LA ACTORA DE LA PATENTE ES 9301319 Y VIOLACIÓN DE LOS MISMOS EN LA FABRICACIÓN Y VENTA POR LA DEMANDADA DE OMEPRAZOL

- 1.- **Noción y regulación de la patente**
- 2.- **Alcance del derecho de exclusiva en el caso de las patentes de producto**
- 3.- **La infracción de una patente por equivalencia**
- 4.- **La falta de toda virtualidad de una eventual alegación en contrario basada en la patente de LABORATORIOS BELMAC, S.A. n° 2192929: artículos 55 y 56 invocables al respecto**

CONFIDENTIAL
EP 004884

-III-

**ACCIONES QUE COMPETEN AL TITULAR DE DERECHOS DE
PATENTE**

- 1.- **Régimen general**
- 2.- **La pretensión de resarcimiento**
- 3.- **La prueba del daño**

-IV-

IMPOSICIÓN DE COSTAS

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AL JUZGADO DE LO MERCANTIL DE MADRID

D^a ALMUDENA GALÁN GONZÁLEZ, Procuradora de los Tribunales, en nombre de la compañía ETHYPHARM, S.A. con domicilio en Madrid, Calle Marqués de la Ensenada nº 16, cuya representación acredito mediante escritura de poder que en forma acompaño, asistida por el Letrado D. ANTONIO CASTÁN PÉREZ-GÓMEZ, ante el Juzgado comparezco y, como mejor proceda en Derecho, DIGO:

Que por medio del presente escrito y en la representación que ostento, formulo demanda de JUICIO ORDINARIO sobre infracción de derechos de patente contra LABORATORIOS BELMAC, S.A. con domicilio en Calle Teide 4, 1 Parque Empresarial La Marina 28700 San Sebastián de los Reyes (Madrid).

Sirven de base a la demanda los siguientes:

HECHOS

PRIMERO.- LA COMPAÑÍA DEMANDANTE ETHYPHARM, S.A. Y EL PLANTEAMIENTO GLOBAL DE LA ACCIÓN QUE SE INTERPONE

La presente demanda tiene por objeto la restitución íntegra de los derechos de patente de la compañía ETHYPHARM, S.A. sobre la tecnología inherente a una patente de invención nº 9301319 que reivindica una "*Formulación estable de microgránulos de Omeprazol y un procedimiento para su obtención que estaba siendo utilizado*". Como pondremos de manifiesto en este escrito la demandada, LABORATORIOS BELMAC, S.A., después de haber mantenido relaciones comerciales con ETHYPHARM, S.A. para la fabricación y venta de Omeprazol bajo la referida patente, puso término a dicha relación y continuó haciendo uso de la formulación patentada en su propio beneficio.

La demandante, ETHYPHARM, S.A., es la filial española de una firma líder en el desarrollo de soluciones farmacéuticas. Con una plantilla de más de 800 empleados

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por todo el mundo, ETHYPHARM cuenta con 5 Centros de Investigación y 3 fábricas en Francia, un Centro de Investigación en Canadá, filiales en India y China y presencia en países como Japón, Italia o Estados Unidos. A lo largo de los años ETHYPHARM, S.A. ha desarrollado y lanzado alrededor de 50 productos en más de 70 países y es reconocida como una de las empresas líderes en tecnología farmacéutica.

Aportamos como DOCUMENTO N° 1, la impresión en papel de la información que sobre el grupo ETHYPHARM puede ser obtenida a través de su sitio de Internet <www.ethypharm.com>.

SEGUNDO.- LA PATENTE DE INVENCION N° 9301319 QUE SIRVE DE BASE A LA ACCIÓN

A) La demandante es titular registral de la patente española número de solicitud 9301319 y número de publicación 2052458. Nos referiremos en adelante al título de la actora bajo la referencia patente ES 9301319. Esta patente fue solicitada el 15 de junio de 1993 y concedida por resolución de 5 de diciembre de 1994. Las reivindicaciones que definen el objeto de esta patente son las siguientes:

"1. Formulación estable de microgránulos de omeprazol que se componen de un núcleo neutro constituido por azúcar y almidón, caracterizada por tener una capa activa constituida por una dilución de omeprazol en manitol en cantidades sensiblemente iguales.

2. Formulación según la reivindicación 1, caracterizada por tener la capa activa de omeprazol sensiblemente 10% en peso de carboximetilalmidón.

3. Formulación según la reivindicación 2, caracterizada por tener la capa activa de omeprazol sensiblemente 5% de un compuesto tensioactivo del tipo laurilsulfato de sodio.

4. Formulación según una cualquiera de las reivindicaciones 1 a 3, caracterizada por tener en la superficie de la capa activa de omeprazol una capa complementaria de protección compuesta por manitol.

5. Formulación según una cualquiera de las reivindicaciones 1 a 4, caracterizada por estar aplicadas la dilución de omeprazol en

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mannitol y dicha capa de protección mediante un agente ligante del tipo de la hidroxipropilmetilcelulosa de gran viscosidad.

6. Formulación según una cualquiera de las reivindicaciones 1 a 5, caracterizada por tener los granos activos una capa externa gastroprotectora compuesta por un recubrimiento gastrorresistente del tipo stálato de hidroxipropilmetilcelulosa y talco.

7. Procedimiento de obtención de la formulación según una cualquiera de las reivindicaciones 1 a 6, caracterizado por serles aplicados a los granos neutros constituidos de azúcar y almidón una dilución seca de manitol y omeprazol mediante una solución ligante del tipo hidroxipropilmetilcelulosa de gran viscosidad en solución en una mezcla de al menos 80% de etanol y 20% de agua como máximo.

8. Procedimiento según la reivindicación 7, caracterizado por tener cada aplicación de la dilución seca un secado a continuación, a una temperatura comprendida entre 35 °C y 40 °C por una duración que permite bajar el contenido de microgránulos activos en agua al 1% y el contenido en etanol a 2 000 ppm.

9. Procedimiento según las reivindicaciones 7 y 8, caracterizado por utilizar microgránulos neutros cuyo tamaño está comprendido entre 0,7 y 0,9 mm.

10. Procedimiento según las reivindicaciones 7, 8 y 9, caracterizado por utilizar para la realización de las aplicaciones de dilución activa y los recubrimientos gastroprotectores turbinas con fondo plano."

Acompañamos como DOCUMENTO Nº 2, la certificación acreditativa de la titularidad y vigencia de la patente ES 9301319 de **ETHYPHARM, S.A.** y como DOCUMENTO Nº 3, el certificado oficial expedido por la Oficina Española de Patentes y Marcas con el texto de dicha patente.

B) La patente de **ETHYPHARM, S.A.** comprende diez reivindicaciones. Las reivindicaciones 1ª a 6ª se refieren a una formulación o producto farmacéutico; la 7ª a 10ª reivindican el procedimiento de preparación u obtención de esta formulación. La característica esencial del primer grupo de reivindicaciones es que la formulación estable de microgránulos de Omeprazol se compone de un núcleo neutro constituido por azúcar y almidón recubierto por una capa activa que comprende una dilución de Omeprazol en manitol en cantidades sensiblemente iguales.

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**TERCERO.- LAS RELACIONES COMERCIALES MANTENIDAS
ENTRE LAS PARTES A PROPÓSITO DEL OMEPRAZOL
FABRICADO CONFORME A LA PATENTE N° 9301319**

A) La demandada LABORATORIOS BELMAC, S.A.

La demanda se dirige contra la compañía LABORATORIOS BELMAC, S.A.. Se trata de una firma constituida en 1991 cuya oficina central se encuentra en San Sebastián de los Reyes (Madrid) y cuya fábrica principal está sita en Zaragoza. Como puede observarse en su sitio de Internet <www.belmac.com> la demandada tiene orientada su actividad hacia los productos que actúan en el aparato digestivo.

Aportamos como DOCUMENTO N° 4, la impresión en papel de la información que sobre la demandada puede ser obtenida en esta página; y como DOCUMENTO N° 5 una nota simple informativa sobre LABORATORIOS BELMAC, S.A. obtenida a través del Registro Mercantil Central.

**B) Los acuerdos suscritos por LABORATORIOS BELMAC,
S.A. con ETHYPHARM, S.A. para la fabricación del
Omeprazol con arreglo a la patente ES 9301319**

Para la fabricación en España de Omeprazol ETHYPHARM, S.A. emprendió relaciones comerciales con la firma LABORATORIOS BELMAC, S.A.. En virtud de los acuerdos suscritos al respecto, la demandada se comprometió con la actora a fabricar en exclusiva para ETHYPHARM, S.A. el Omeprazol cuya orden de pedido recibiese de mi representada y a comprar también de ETHYPHARM, S.A. el Omeprazol cuyos pedidos pudiese recibir de sus propios clientes. La razón era muy simple: mi representada facilitó a LABORATORIOS BELMAC, S.A. el soporte tecnológico necesario para la fabricación del Omeprazol con arreglo a la patente ES 9301319.

Acompañamos en prueba de lo anterior y como DOCUMENTO N° 6, el contrato de fabricación de 23 de marzo de 2000 y el contrato de compromiso de compra de igual fecha por el que se formalizan las bases de la relación comercial que habían mantenido a lo largo de los años ETHYPHARM, S.A. y LABORATORIOS

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